JC10 Rec'd PCT/PTO 94 MAY 2005

ATTORNEY'S DOCKET NUMBER FORM PTO-1390 (REV. 1-2003) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE 512100-2046 TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (If known see 37 C.F.R. 1.5) DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A FILING UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE DRITY DATE CLAIMED PCT/EP2003/011529 17 October 2003 8 November 2002 TITLE OF INVENTION TRANSMUCOSAL PHARMACUETICAL ADMINISTRATION FORM APPLICANT(S) FOR DO/EO/US Hoffmann et al Applicants herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371. This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected. A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. A have not been made and will not be made. A English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. **EXPRESS MAIL** 13. A preliminary amendment. 14. An Application Datasheet under 37 CFR 1.76. Mailing Label Number: EV 196816042 US 15. A substitute specification. Date of Deposit: 4 May 2005 I hereby certify that this paper or fee is being deposited 16. A power of attorney and/or change of address letter. with the United States Postal Service 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and 18. A second copy of the published international application under is addressed to: Mail Stop PCT, Commissioner for 35 U.S.C. 154(d)(4). Patents, P.O. Box 1450, Alexandria, VA 22313-1450. 19. A second copy of the English language translation of the)9(K international application under 35 U.S.C. 154(d)(4). (Typed or printed name of person mailing paper or fee) Other items or information: preliminary amendment; PCT/IB/308; PCT/ISA/210; PCT/RO/101; references cited in (Signature of person mailing paper or fee) IDS

| page 2 of 2 | | | | | |
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| U.S. APPLICATION NO | | | TIONAL APPLICATION NO. T/EP2003/011529 | ATTORNEY'S DOCKET NO. 512100-2046 | |
| 21. The following fees are submitted | | | | CALCULATIONS PTO USE ONLY | |
| BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO\$1110.00 | | | | | |
| International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO\$950.00 | | | | | |
| International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO\$790.00 | | | | | |
| International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)\$750.00 | | | | | |
| International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) | | | | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = | | | | \$ 950.00 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than \(\bigcup 20 \) \(\bigcup 30 \) months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | \$ | |
| CLAIMS | NUMBER FILED | te (37 CFR 1.492(e)). NUMBER EXTRA | RATE | \$ | <u> </u> |
| Total Claims | 11 - 20 = | 0 | x \$18.00/\$9.00 | \$ | |
| Independent Claims | 1 3 = | 0 | x \$88.00/\$44.00 | \$ | - |
| | DENT CLAIM(S) (if a | | + \$300.00/\$300.00 | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ 950.00 | |
| Applicant claims small entity status. See 37 C.F.R. 1.27. The fees indicated above are reduced by ½. | | | | \$ | |
| SUBTOTAL = | | | | \$ 950.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | \$ | · . |
| TOTAL NATIONAL FEE = | | | | \$ 950.00 | |
| Fee for recording the enclosed assignments (37 CFR 1.21(h)). The assignment must be | | | | \$ 40 | |
| accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + TOTAL FEES ENCLOSED = | | | | \$ 990.00 | |
| | | X O X TEC I DE | 3 Li (CLOOLD | Amount to be refunded: | \$ |
| | | | | Charged: | \$ |
| a. A check in the amount of \$ 990.00 to cover the above fees is enclosed. | | | | | |
| b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | |
| c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0320. A duplicate copy of this sheet is enclosed. | | | | | |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization | | | | | |
| on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. | | | | | |
| A. 11/1. | | | | | |
| SEND ALL CORRESPONDENCE TO: SIGNATURE | | | | reep | |
| William F. Lawrence, Esq. | | | | | |
| Frommer Lawrence & Haug LLP 745 Fifth Avenue William F. La | | | William F. Lawr | ence, Esq. | |
| New York, New York 10151 NAME | | | | | |
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| Dateu. V4 May 2003 | | | REGISTRATION NUM | MBER 28,029 | ······································ |

<u>CERTIFICATE OF MAILING - SEPARATE PAPER - PATENT APPLICATION</u>

Attorney Docket No.:

512100-2046

Title:

TRANSMUCOSAL PHARMACEUTICAL

ADMINISTRATION FORM

Filed

Herewith

Applicants

Hoffmann et al

Mailed: May 4, 2005 via "Express Mail Label # EV 196816042 US

I hereby certify that the Patent Application for the above-referenced application and accompanying papers are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

MAIL STOP PCT Assistant Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Enclosed:

Transmittal Fee Letter

Application for Patent

(5 pages of specification, 2 pages of claims, numbered 1-11)

preliminary amendment, PCT/IB/308; PCT/ISA/210; PCT/RO/101; Information Disclosure Statement, PTO Form 1449, and cited references Combined Declaration for Patent Application and Power of Attorney

Assignment and Recordation Cover Sheet

Check in the amount of \$990.00

Return Receipt Postcard

(Type/printed name of person mailing paper or fee)

Signature